Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

London, 15 March 2011

REPORT FOR RELEASE: January – February 2011

January 2011 product discussions

Seven products reached day 210 of the decentralised procedure (DCP).

	MRP	DCP	Referrals
Procedures	0	8	3
Products*:	0	7	1
Immunological	0	0	0
Pharmaceutical	0	7	1

* 1 product includes all strengths submitted but does not include duplicate applications, which are counted separately

Agreement was reached on the granting of marketing authorisations (MAs) for six of the seven products. No agreement was reached on the granting of marketing authorisations for 1 product, which was consequently referred to CMDv pursuant to Article 33(1) of Directive 2001/82/EC, as amended, for a 60-day referral procedure. The grounds for referral were potential serious risk to animal health and public health due to outstanding concerns on environmental safety and the withdrawal period.

February 2011 product discussions

Seven products reached day 90 of the mutual recognition procedure (MRP) and eleven products reached day 210 of the DCP;

	MRP	DCP	Referrals
Procedures	8	11	0
Products*:	5	11	0
Immunological	0	0	0
Pharmaceutical	5	11	0

* 1 product includes all strengths submitted but does not include duplicate applications, which are counted separately

Agreement was reached on the granting of marketing authorisations (MAs) for all products.

CMDv referral procedures

Three referral procedures reached day 60 in January and were finalised but one strength of the product was referred to CVMP pursuant to Article 33(4) of Directive 2001/82/EC, as amended, as the outstanding concerns remained unresolved. See table below for details.

Proc. no.	Product	Active subs.	Pharm. form	Legal basis	CMS	D60	Grounds for ref.	Outcome
UK/V/0373/ 001/MR	Clavudale 50 mg	Amoxicillin, clavulanic acid	Tablets	Art 13 generic	AT, BE, CZ, DE, DK, EL, ES, FI, FR, HU, IE, IS, LU, NL, NO, PL, PT, SE, SK	21 Jan 2011	Potential serious risk to animal health due to expression of the product strength as a combined total for both active substances (risk of under-dosing) and demonstration of bioequivalence not accepted for cat target species	Not resolved, referred to CVMP under article 33(4)

Update and Advice to Applicants

2010 procedure statistics

The following is an overview of the statistics for procedures in 2010. The figures below are still undergoing review and may be subject to minor corrections but give a general overview at the present time:

Overall: 156 = 99 DCP + 57 MRP (25 RUP) for 109 products

RMS: 14 MS (UK: 40; IE: 23; NL: 21; DE: 17; FR, ES: 13; IT: 8; AT, CZ, HU: 5; DK, SE: 2; NO, PT: 1)

Target species: Food producing animals: 82, companion animals: 74

Legal basis: art. 12(3): 18
art. 13(1): 121 (approx. 75% of all marketing authorisation applications)
art. 13a: 9
art. 13c: 1
annex II (line extension): 5

Type of product: pharmaceutical: 152, immunological: 4

Referral procedures to CMDv: 8

Referral procedures to CVMP: 3

CMDv working groups

There has been a change in terminology: CMDv subgroups will be replaced by the term CMDv working groups. The mandate for the new working group on borderline products will be discussed in March.

Variation worksharing requests

In February, two worksharing requests were received – one informal procedure since purely-national MAs were included and one formal procedure involving only MRP/DCP MAs. The designated reference authority in each case was Germany, Paul-Ehrlich-Institut.

Electronic submission

CMDv finalised a questionnaire on the acceptance of the use of Eudralink by Member States for different types of regulatory (electronic) submissions. The email addresses to be used for e-submission via Eudralink were also collected as part of the questionnaire and were passed on to the EMA's TIG-es vet subgroup. The results of the questionnaire show that a number of Member States are in principle happy for submissions to be made via Eudralink for procedures other than the first marketing authorisation application (dossier is usually too big, some Member States still require a signed cover letter). However there are a few Member States who cannot work with submissions via Eudralink due to of archiving issues. Other important points agreed by CMDv on the subject of e-submission were:

- A hyperlinked/bookmarked table of contents should be a mandatory validation requirement;
- Multiple files sent via Eudralink should always be zipped (this should be a validation criteria).
- Eudra mailboxes should never be used by external users.

February interested parties meeting

This meeting took place on 11th February and the CMDv Chair provided the interested parties, EGGVP, IFAH-Europe and AVC, with a de-brief of the main points discussed by CMDv since the last interested parties meeting. Questions raised by the interested parties were discussed, including:

- the provision of user risk assessment and environmental risk assessment at renewal – should not be requested unless a change is identified to the benefit-risk balance for the product;
- the requirement by some Member States for one SPC per strength of a product – this will be further discussed by CMDv.

The consultation comments from the interested parties on the Best Practice Guides for repeat-use MRP (BPG 003) and on informed consent (BPG 012) were discussed. Regarding repeat-use MRP, there was discussion on whether a renewal was mandatory in the new CMS following a repeat-use procedure, even if one renewal has already taken place for the product in the 'old' CMS. CMDv confirmed their understanding that one renewal should systemically take place in the new CMS. The document will be further discussed by CMDv in March, with a view to being finalised and adopted.

Regarding informed consent, the differing submission requirements of Member States for informed consent applications were discussed (e.g. only Part I or also Part II) and CMDv would collect information on this for possible inclusion in the best practice guide. The document will be further discussed by CMDv in March.

HMA working group on product testing

CMDv received a report from this working group and it was requested that the CMDv secretariat would provide quarterly figures on the number of MRP/DCP applications started in 2011 for the pilot phase I: testing of the risk-based criteria for the selection of products for testing by inspectors and Official Medicines Control Laboratories, with the aim to draft and adopt EU guidance based on the outcome of this pilot phase. Quality assessors would be required to complete a short template for the assessor-identified risk factors during 2011. Eventually, this template, in combination with other risk-based criteria, would determine whether a product is selected for testing.

CMDv Q&As

The Q&A on extension of the implementation by Member States of Variation Regulation 1234/2008 to products authorised on a purely-national basis was finalised and published in December – click here for link.

A new question was received from industry on the date of implementation of the revised CVMP guideline on stability testing (EMEA/CVMP/QWP/846/99-Rev.1). CMDv concluded that, in general terms, it is not appropriate for reference to be made to the revised stability guideline (EMEA/CVMP/QWP/846/99-Rev.1) during assessment of an application prior to the coming into effect of this revision on 1st September 2011. This is due to legal principles and also the fact that, before coming into effect, a guideline may be subject to change, particularly when the contemplated effective date is still some time away.

CMDv documents and guidance

The 2011 workplan was adopted in January and published on the CMDv website – click here for link.

The Best Practice Guide (BPG) for the classification of unforeseen variations was adopted and published – click here for link.

A first draft of the new CMDv document entitled, "Recommendation for Mutual Recognition Procedure after finalisation of an article 34 referral procedure with a positive decision by the EC" was sent to interested parties following the February CMDv meeting for a three-month consultation period.